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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,404	03/31/2004	Samuel Achilefu	MRD-54DV (1515.1 US)	5388
27805	7590	07/29/2008		
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			07/29/2008 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/814,404

**Applicant(s)**

ACHILEFU ET AL.

**Examiner**

MELISSA PERREIRA

**Art Unit**

1618

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-14, 16, 17, 19 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 17, 19 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1,4-14,16,17,19 and 23 are pending in the application. Claims 4-14 and 16 are withdrawn from consideration. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/8/08 has been entered.

### ***Response to Arguments***

Applicant's arguments filed 4/8/08 have been fully considered but they are not persuasive.

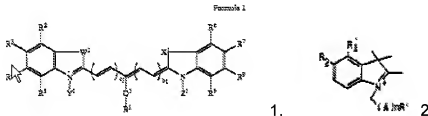
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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- Claims 1,17,19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Achilefu et al. (US 6,180,085B1) as stated in the office action mailed 1/17/08.
- Achilefu et al. (US 6,180,085B1) discloses compositions of formula 1 (below) which are prepared via intermediates, such as that of formula 2 where R<sub>1</sub> and R<sub>2</sub> may be hydrogen (2,3,3-trimethyl-4,5-benzo-3H-indolene) (below) (fig 1, sheet 1; column 2, lines 45-54):



Y<sup>1</sup> of the composition of formula 1 may be  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2H$ , etc. (column 2, lines 63) which encompass the substituents of the instant claims. It would have been obvious at the time of the invention that the intermediate of formula 2 (2,3,3-trimethyl-4,5-benzo-3H-indolene) must be substituted with the same Y<sup>1</sup>, such as  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2H$ , etc. in place of the (A)<sub>n</sub>R group (formula 2) in order to generate the final compositions of formula 1. The  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2H$ , etc. substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Achilefu et al. encompass the compositions of the instant claims.

Applicant asserts that they have amended the claim 1 to limit T, in the Y<sup>1</sup> structure  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2T$ , to a negative charge. Thus, applicants believe that the rejection is overcome.

At the time of the invention it would be obvious to one ordinarily skilled in the art that the  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2H$ , etc. substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Achilefu et al. may be the  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2^-$  derivative as one skilled in the art would know that the structures are analogous. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. One skilled in the art would also know how to prepare the  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2^-$  derivative.

Also the reference of Achilefu et al. teaches that the final compounds of the disclosure may be contained/stable in buffers (column 10, lines 9 and 14) and therefore it is obvious that the intermediates  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2^-$  derivative may be contained/stable in buffers, such as basic buffer solutions.

***Conclusion***

No claims are allowed at this time.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELISSA PERREIRA** whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/  
Examiner, Art Unit 1618